Section IV: 510k Summary

MAY 17 2013

Applicant's Identification

Applicant	Cotronic Technology Limited
Phone Number	+852-2602-2021 / +86-755-8145-3681
Fax Number	+852- 2609-4485 / +86-755-8145-3080
Contact Person	Ms. Tani Mok
Date of Application	1st March, 2012
Date of Summary	13th March, 2013

Device's Identification

Device Proprietary Name	Digital Pacifier Thermometer (Model No.: TM-03)
Common Name	Clinical Electronic Thermometer
Classification Name	Thermometer, Electronic, Clinical (Class II per 21 CFR 880.2910)

Marketed Devices to which Equivalence is Claimed

DEVICE	MANUFACTURER	510(k) Number
Microlife Digital Pacifier Thermometer, Model MT1751Q	Microlife Intellectual Property GmbH, Switzerland	K051100

Device Description

Digital Pacifier Thermometer TM-03 is a reusable, battery-operated clinical electronic thermometer, with which a thermistor installed inside the nipple, for use by medical professional or at home. Different from the traditional electronic thermometer, our TM-03 is designed specifically for the measuring the oral temperature of baby or little child. Therefore, our TM-03 is molded as a pacifier. The patient contact portion is the thermometer's nipple which is made of medical silicon rubber. The body of TM-03 is then manufactured by ABS hard plastic.

TM-03 utilizes the phenomenon of thermal conductivity changes of our selected NTC thermistor when there are changes of external environment temperature. Whenever the external temperature changed, the resistance of our thermistor changed uniformly. Then, the changes in resistance are converted to the changes of frequency of R-C oscillator circuit. This means TM-03 keep monitoring the frequency of the oscillator and the temperature can be measured accurately.

Intended Use (Indication for Use)

Digital Pacifier Thermometer TM-03 is a non-sterile, reusable & battery-operated clinical electronic thermometer for use by medical professional or at home. The TM-03 is intended to measure the oral temperature of infant to children up to 5 years old.

Comparison of Technological Characteristics between New Device and Predicate Devices

Our Digital Pacifier Thermometer TM-03 is non-sterile, reusable & battery-operated clinical electronic thermometer and utilizes the phenomenon of thermal conductivity changes of NTC thermistor to measure the oral temperature reading of infant/children. The key components of device are a NTC thermistor, silicon nipple & a ABS hard plastic body. The predicate device adopts exactly same methodology and key components for measuring the infant's oral temperature.

A comparison table between New Device and Predicate Device is listed as below:

Item	Predicate Device (Microlife MT1751Q Digital Pacifier Thermometer)	TM-03
Product Design	Dummy-like Shape	Equivalent
Temperature Measurement Technology	NTC Thermistor Resistance Technique	Equivalent
Key Temperature Sensor	NTC Thermistor	Equivalent
Material	Resistances, capacitances, transistors, buzzer, MCU, a thermistor, button key, PCB, silicon, ABS plastic cabinet, battery	Equivalent
Energy Source	1 x SR 41battery	1 x LR41 battery
Measurement Time	Around 5 minutes	3 – 5mins

Clinical & Non-clinical Tests

A systematic & independent clinical test was conducted to validate the performance of the Digital Pacifier Thermometer (Model No. TM-03). The results demonstrated that our device (Model No. TM-03) meets the requirement of +/-0.2°F for 95°F – 107.6°F. Also, we have asked an independent laboratory to test the accuracy of our device (Model No. TM-03) based on the ASTME1112 and the results further verified our device meets the requirement of +/-0.2°F for 95°F – 107.6°F.

For the electrical safety of our device, comprehensive testings were carried out according various international standards. Firstly, our devices are tested and compiled with the EN60601-1 (Standard Title: Medical Electrical Equipment Part 1: General requirements for safety), which includes a collective of safety tests. Then, the electrical safety of our devices is further verified via conducting the electromagnetic compatibility test according to FCC Part 15 and IEC60601-1-2. The results classified and demonstrated our devices as Class B device and are compiled with the acceptance limit (40dB (uV/m)).

Furthermore, we have conducted various tests on the safety of material to verify our device (Model No. TM-03) was made by safe material. Firstly, we applied the ISO10993 sets to test the biocompatibility of our device. The results showed no evidence of causing delayed dermal contact sensitization. And our device is classified as a non-irritant and not a cytotoxic potential. Secondly, we tested the silicon nipple of our device with US Compliance Policy Guide Part 7117.11 for nitrosamine content in rubber baby bottle nipples. We notice that the testing scope of Policy Guide Part 7117.11 was not applicable to our product category. However, we still would like to have a reference on the safety towards nitrosamine content in our device (Model No. TM-03). The results demonstrated our device is safe and within the corresponding acceptance limit (10ppb). Thirdly, our device/device components not made with BPA. BPA is not used in the manufacture of the accessible parts of the device (TM-03).

Comprehensive safety and EMC tests were performed and compiled to demonstrate (Model No.TM-03) is safe for use. Tests include

1. Biological evaluation of medical devices --- Part10: Tests for irritation and skin sensitization
2. Biological evaluation of medical devices --- Part12: Sample preparation and reference materials
3. Biological evaluation of medical devices --- Part 5: Tests for In Vitro Cytotoxicity
4. Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
5. CFR Title 16 Part 1511 - Requirement for pacifiers
6. CPG Sec. 500.450 Volatile N-Nitrosamines in Rubber Baby Bottle Nipples
7. Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Requirement
8. Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance

Conclusion

Our Digital Pacifier Thermometer TM-03 has the same intended use and similar technological characteristics as predicate device (K051100). Moreover, bench testing contained in this submission and clinical testing supplied demonstrated that no differences in the technological characteristics and questioning on safety or effectiveness to be raised. Thus, the Digital Pacifier Thermometer TM-03 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 17, 2013

Ms. Tani Mok
Cotronic Technology, Limited
Floor 4-6, Block 7, West of Zhoushi Road
Xixiang Street Baoan Zone, Shenzhen,
Guang Dong Province, China 518126

Re: K120671
Trade/Device Name: Digital Pacifier Thermometer (Model No.: TM-03)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: April 24, 2013
Received: May 16, 2013

Dear Ms. Mok:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

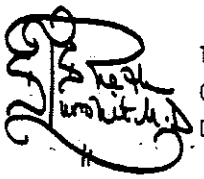
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section V: Statement of Indications for Use

510(k) Number (if known): K120671

Device Name:

Digital Pacifier Thermometer (Model No.: TM-03)

Indications For Use:

Digital Pacifier Thermometer TM-03 is a non-sterile, reusable & battery-operated clinical electronic thermometer for use by medical professional or at home. The TM-03 is intended to measure the oral thermometer of infant to children up to 5 years old.

Prescription Use _____ **AND/OR** **Over-The-Counter Use** __X_____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120671